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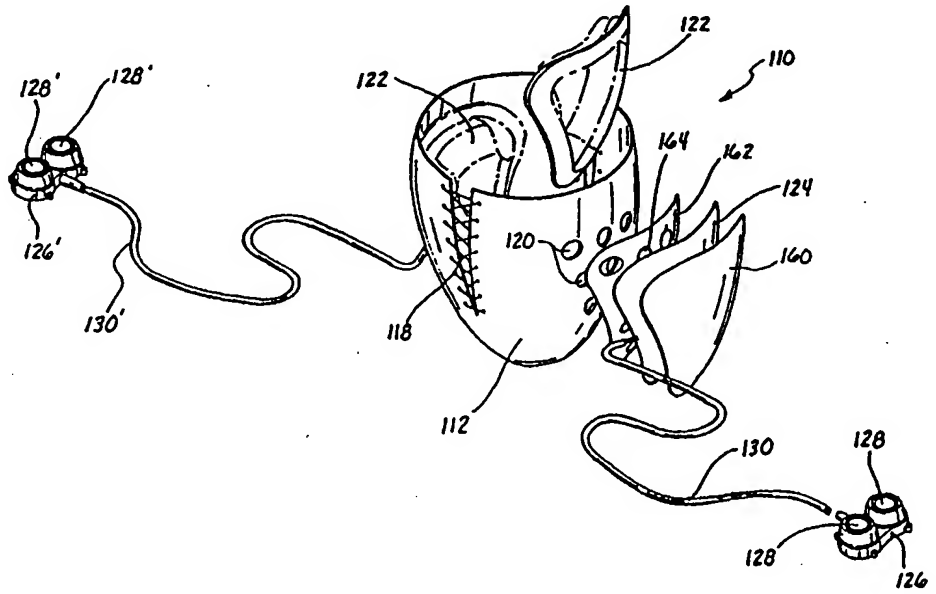
(54) Title: METHOD AND APPARATUS FOR REINFORCEMENT OF THE HEART VENTRICLES



(57) Abstract

A unique device is provided for treating heart disorders, and particularly cardiomyopathy. The inventive device is comprised of a compliant containment structure (110) shaped in a configuration such that it surrounds and encases the heart. Within this containment structure are housed two or more inflation pockets (122) that are fabricated from a non-elastic compliant material. These pockets are disposed on the interior surface of the containment structure and are configured to oppose and support the external wall of at least one of the ventricles of the heart. In the preferred embodiment, there are a plurality of relatively small, spaced inflation pockets disposed to act against each ventricle which is to be contained.

METHOD AND APPARATUS FOR REINFORCEMENT OF THE HEART VENTRICLES

This application claims the benefit of U.S. Provisional Application Serial No. 60/113,232, filed December 21, 1998, which is commonly owned and the contents of which are expressly incorporated herein by reference.

Field of the Invention

The present invention relates to devices and methods for treating cardiomyopathy, a chronic disorder of the heart muscle, and more particularly to an implantable ventricular restraint device which is adapted to confine and control ventricular diastolic expansion.

Background of the Invention

Cardiac dilation occurs with various diseases of the heart, including heart failure. In some instances, such as ischemic heart disease, the dilation may be localized to only a portion of the heart. On the other hand, cardiomyopathy usually results in global impairment. In the case of hypertrophic cardiomyopathy, there is typically increased resistance to filling of the left ventricle with accompanying dilation of the left atria. In dilated cardiomyopathy, the dilation is typically of the left ventricle with resultant failure of the heart as a pump. As the ventricles become enlarged, the situation is worsened by the resultant leakage which develops around the valvular structures. A sharply reduced ejection fraction is the hallmark of this condition.

Dynamic cardiomyoplasty is one treatment currently being used to treat cardiomyopathy. One current approach being used to treat this disorder is a procedure that involves wrapping and attaching a portion of a patient's own latisimus dorsi muscle around the heart, as described, for example, in the article

for a maximum remodeling of the heart may be reduced. Another drawback to the disclosed approach of Alferness is that the disclosed device applies a uniform force to both right and left ventricles. Typically, the left ventricle is the one that causes the disorder as it operates at much higher pressures. This design does not provide the medical professional with any means to accurately optimize or monitor the device's therapeutic effect. The optimal operating parameters for the device may vary dramatically from patient to patient, and these parameters can again change over time as the patient's heart becomes accustomed to the device or goes through a remodeling phase. There is typically a very small imbalance in operating forces that causes the problem and therefore a very small force is sometimes all that is required to correct the condition. Consequently, in the event that the patient were to have an adverse reaction to the device's preset configuration, an urgent surgical intervention would need to be performed to remedy the problem.

What is needed, therefore, is an improved ventricular reinforcement device which may be conveniently re-sized without surgical intervention as the heart remodels to its normal size, and which is capable of independently applying selectively differing forces against the right and left ventricles of the diseased heart.

Summary of the Invention

The present invention addresses the problems outlined above by providing a unique device for treating heart disorders, and particularly cardiomyopathy, comprised of a compliant containment structure shaped in a configuration such that it surrounds and encases the heart. Within this containment structure are housed two or more inflation pockets that are fabricated from a non-elastic compliant material. These pockets are disposed on the interior surface of the containment structure and are configured to oppose and support the external wall of at least one of the ventricles of the heart. In the preferred embodiment, there are a plurality of relatively small, spaced inflation

Fig. 8 is a cross-sectional view similar to Fig. 7, illustrating a portion of the device shown in Figs. 3 and 4, during the fluid exchange phase;

Fig. 9 is a perspective view of the containment structure which forms a part of the inventive device;

Figs. 10A and 10B are plan views, in isolation, of the inflation pockets which form a part of the inventive device;

Fig. 11 is a plan view, in isolation, of the recoil plate which forms a part of the second configuration of the inventive device illustrated in Figs. 3 and 4;

Fig. 12 is a schematic view illustrating the placement of the fluid access port which forms a part of the present invention;

Fig. 13 is a schematic view illustrating yet a third embodiment of the inventive device;

Fig. 14 is a perspective view illustrating a fourth preferred embodiment of the invention;

Fig. 14a is a perspective view illustrating a modified version of the fourth embodiment shown in Fig. 14;

Fig. 14b is a cross-sectional view of a portion of the embodiment illustrated in Fig. 14a;

Fig. 15 is a front elevational view showing the embodiment of Fig. 14 after it has been placed about a heart, with a bypass graft in place;

Fig. 16 is a cross-sectional view of the embodiment illustrated in Fig. 14, showing in detail the inflation pockets of the invention;

Fig. 17 is a conceptual graphical plot of the cyclical pressure measured by an external pressure monitor for the device illustrated in Fig. 14 when it is installed on a heart and working full time (i.e. in contact with the heart full time);

Fig. 18 is a conceptual graphical plot similar to that of Fig. 17 of the cyclical pressure measured by an external pressure monitor for the device illustrated in Fig. 14 when it is installed on a heart but not in contact with the external surface of the heart full time (i.e. it needs to be re-sized by addition of fluid); and

It should be noted that, for example, as an alternative to lacing up the slits 14, VELCRO hook and loop fastening straps 18a, 18b may be provided along each side of the slit. This alternative is illustrated in Fig. 2a. During the placement of the device, the VELCRO straps 18a are overlapped to provide an accurate fit, then sutures 19 are made through the VELCRO overlap to secure the sizing permanently.

Port holes 20 are preferably provided in the frame 12 to provide a fluid flow path and permit the exchange of fluid from a plurality of inflation pockets 22 (Fig. 1) to a recoil balloon 24. The inflation pockets 22 (in this embodiment two are provided) are preferably formed of a composite structure made from a high strength biocompatible mesh-like material such as polyester fully encased within a flexible biocompatible material such as silicon or polyurethane (this may be the same material from which the frame or containment structure 12 is fabricated). These components essentially comprise balloons which are flexible and compliant with very low elasticity. Their purpose is to support the outer wall of the heart ventricle. Very low elasticity is desirable because in use there is a requirement that fluid contained within the inflation pockets 22 be expelled through the frame 12 when the pockets 22 are compressed. Consequently, a volume change due to volumetric expansion would be undesirable, as it would compromise the fit of the device on the heart. Preferably, the two provided inflation pockets 22 are of different configurations, and are asymmetrically located, due to the fact that the respective ventricles which they support are different in both configuration and location, with the left ventricle being much larger than the right ventricle. It should be noted that it is within the scope of the invention to provide more than two inflation pockets 22 if desired, since configurations wherein more than one pocket 22 supports a single ventricle may be potentially beneficial in certain instances. Such an embodiment, presently preferred, is illustrated in Figs. 14-16.

The recoil balloon 24 is preferably fabricated of a thin high elasticity biocompatible material such as silicon or polyurethane. This component

provided on the opposing side of the frame 112 for operation with the second inflation pocket 122 (not shown). A pressure isolator plate 162, having a plurality of port holes 164, is disposed between the frame 112 and the inner recoil balloon 124. The pressure isolator plate, or recoil plate 162, is preferably made of a rigid plastic material. Additionally, a second fluid access port 126' is provided, having two septa 128' and a fluid line 130'. The fluid access port 126 is arranged to supply fluid to the two recoil balloons 124 and 160 disposed on one side of the frame 112, splitting at the bifurcation 136 (Fig. 3) so that the tube 138 from one lumen supplies the recoil balloon 124, and the tube 140 from the other lumen supplies the recoil balloon 160. Similarly, the fluid access port 126' independently supplies the two recoil balloons (not shown) disposed on the other side of the frame 112. Thus, the practitioner may independently and selectively supply differing quantities of fluid to each of the two recoil balloons disposed in a set on each side of the frame 112, and also independently supply fluid to each set of recoil balloons. In other words, all of the recoil balloons, whether in the same set or in different sets, are isolated from one another, and may be independently pressurized.

The second recoil balloon 160 may be comprised of the same material as the first recoil balloon, or it may alternatively have different material properties. A second fluid chamber 166 (Fig. 6) is provided between the first and second recoil balloons.

The pressure isolator plate, or recoil plate 162 is utilized only in the second embodiment because when the secondary recoil balloon 160 is partially inflated, it puts a compressive load on the inner recoil balloon 124, which in turn compresses the frame wall causing increased pressure on the inflation pocket 122. The purpose of the plate 162 is to isolate those forces.

In yet a third embodiment of the invention, the system may be constructed as shown in either the first or second embodiments. The only change is that, as illustrated in Fig. 13, in this embodiment the fluid access port 26, 126, 126' is augmented by a pressurized fluid reservoir system 280 having a one-way valve

which may be present on the patient's heart 385. A device constructed as illustrated in the first three embodiments may not be as suited to this type of condition, because the inflation pocket may cover and compress the bypass vessel, causing a restriction in the blood flow. In addition, in severe cases of cardiomyopathy (large dilation of the heart), there may not be sufficient space for the recoil balloons to expand without being compressed against the surrounding anatomy if they are attached to the side of the inventive device, as shown in the embodiments of Figs. 1, 2, and 3. This compression would, of course, affect the pressures at which the device operates.

In contrast, the present embodiment comprises a plurality of multiple small inflation pockets 322, rather than the fewer, larger inflation pockets disclosed in the previous embodiments. The multiple inflation pockets 322 simulate the appearance of bubble wrap, but are spaced apart enough to provide a sufficient clearance between them to accommodate an existing bypass graft 384, or to allow a subsequent bypass graft 384 to be attached. Because the inflation pockets 322 are spaced, and small, no one pocket 322 should cover and compress the bypass vessel sufficiently to cause undesirable blood flow restriction. If, however, that is the case, because of the number of inflation pockets 322, one or more of them can be removed during the installation procedure to accommodate the existing bypass graft 384.

Furthermore, this preferred embodiment overcomes the problems discussed supra, related to the unavailability of sufficient space for the recoil balloons of the prior embodiments in the event of a severely enlarged heart, by reducing the side profile and relocating the recoil balloons away to a location where space is not at a premium. The device otherwise functions in substantially the same manner as in the previous embodiments.

Preferably, when it is necessary to perform a bypass procedure subsequent to installation of the device 310, the bypass graft is routed around the exterior surface of the structure 312. The large number of access holes 320 provided in the mesh material increase the likelihood that the graft can be

structure 312, rather than being attached to the exterior surface of the frame 312, as in prior embodiments. As in the prior embodiments, the balloons 324 are preferably fabricated of a thin high elasticity biocompatible material such as silicon or polyurethane. This arrangement offers the benefit of reducing the space that the device occupies immediately around the heart, and instead permits the disposition of the balloons 324 elsewhere in the chest cavity where space may not be as restricted. One other advantage of this construction is that the balloons may be changed out by utilization of only a minor surgical procedure, involving only the removal of easily detachable fittings 387 (Fig. 14), such as Luer Locks, in the event that balloons with different pressure capacity or recoil properties would be of benefit.

Another version of this preferred embodiment is illustrated particularly in Figs. 14a and 14b. This embodiment is very similar to that of Fig. 14, except that a double recoil balloon, comprised of a pair of inner and outer recoil balloons 324, 360 is utilized, rather than a single recoil balloon 324. This is similar in concept to the embodiment illustrated in Fig. 4, with back-to-back recoil balloons 124, 160. As shown, the detachable fitting 387 comprises a male Luer Lock 387a and a female Luer Lock 387b. Lumen 330a provides a fluid line for filling the inner balloon 324, while lumen 330b provides a fluid line for filling the exterior balloon 360. A fluid line block 330c forces fluid to enter the outer balloon 360 through an entry port 330d. Passage 387c in the female Luer Lock 387b provides an exit port for fluid exiting the interior recoil balloon 324 for the inflation pockets. In operation, when fluid is injected into the cavity 360a between the exterior balloon and the interior balloon, the exterior balloon 360 becomes distended and causes an increase in the filling pressure for the interior balloon 324. This configuration thus, as is apparent, provides a convenient method for increasing operating pressures, if desired, and thereby perhaps avoiding undue intervention.

Another advantageous feature of the present embodiment is its capability to directly deliver Trans echocardial drugs to the pericardium. In a preferred

the fluid access port 26, 126, 126', 326 and the fluid is injected. The injected fluid fills the fluid access port, the inflation delivery line 30, 130, 130', 330', flows through the recoil balloons 24, 124, 324, and finally enters the inflation pockets 22, 122, 322. The pressure of the inflation pockets is monitored by a pressure wave, which occurs as the ventricle empties and refills. The fluid level is increased in the pockets until there is always a positive pressure present. This indicates that the inflation pockets 22, 122, 322 are in contact with the ventricle when it is systolic. Figs. 5 and 7 illustrate each of the first and second disclosed embodiments wherein the inflation pockets 22 and 122, respectively, are in their filled state.

In the third embodiment, shown in Fig. 13, pressurized fluid will initially be introduced into the system from the pressurized fluid reservoir 280, through the one-way valve 282, rather than manually via a syringe. In all other respects, operation of the third embodiment is substantially similar to that described above with respect to the first, second, and fourth embodiments, and, in fact, any of the first, second, and fourth embodiments can utilize an automated fluid pressurization system as shown in the third embodiment.

Once the device 10, 110, 310 has been initiated, or activated, it functions by assisting the failing and dilating heart muscle. The device provides a substantially constant external restraining force, which increases as the ventricle goes from a systolic to a diastolic state. As a ventricle is filled, it dilates and compresses its adjacent inflation pockets 22, 122, 322. This, in turn, reduces the volume of the inflation pockets. This is because, in the first two embodiments, the fluid is permitted to escape through the port holes 20, 120 in the frame 12, 112 into the recoil balloon 24, 124 on the external surface of the frame 12, 112, as shown in Figs. 6 and 8, respectively. The fourth embodiment operates a little differently, because the recoil balloons 324 are disposed remotely from the containment structure 312, in the fluid lines 330. In this embodiment, as the fluid pressure increases, the fluid is displaced from the inflation pockets and is permitted to escape in a backwards direction through the fluid tubes 386 into the

additional available fluid access port. Fluid forced into this space 166 will stretch the surface of the balloon 160, as illustrated in Fig. 7, thereby creating a greater resistance to the filling of the inner recoil balloon 124, which in turn increases the restraining force placed upon the heart. This adjustment may be made to any or all recoil balloons, as desired.

A major advantage of this design is that if a patient has an adverse reaction to the restraining forces of the frame 12, 112, 312 immediate relief may be obtained by removing fluid from the inflation pockets via the fluid access ports 26, 126, 126', 326.

It should be noted, as another advantageous feature of the invention, that the inflation pockets disclosed in any of the foregoing embodiments may be coated, if desired, with a drug infused osmosis material. If this is the case, the drug may leach out slowly for a term immediately after placement of the inventive device over a patient's heart, thereby aiding recovery.

Referring now, in particular, to Figs. 17-19, there is illustrated a minimally invasive arrangement for monitoring and accurately measuring diastolic and systolic pressures and performance in an entirely new way. This data can be used for diagnostic purposes, to optimize the adjustment of the device, and/or to monitor therapy. In order to achieve this, the fluid access port 26, 126, 326 of the device 10, 110, 310 is directly attached, via a connecting flow line 492, to an external pressure monitoring system 493 (Fig. 19). This system may comprise a monitor, or a pulsating pump. To create a closed loop, a needle 494 is placed into the elastomeric septum 28, 128, 328, which, in turn, is attached to the connecting flow line 492 using, for example, a Luer lock connector 494a. Under normal operating conditions, diastolic expansion will cause the pressure inside the device to increase, and systolic contraction will cause the pressure to decrease. This pressure change occurs along the entire fluid path between the device and the pressure monitoring system, so that the monitoring system 493 receives data that translates into a complete pressure wave, as illustrated in Figs. 17 and 18, which each represent generalized plots of pressure change over time.

as being adapted for restraining both ventricles of the heart, it is clearly within the scope of this invention to install the device 10, 110, 310 in such a manner that only one ventricle is restrained. Typically, this one ventricle will be the left ventricle, as this is the one which typically causes the cardiomyopathy condition.

inflation pocket, thereby forcing fluid from said inflation pocket through said fluid passage and into said recoil balloon.

7. The device as recited in Claim 6, wherein when said heart enters a systolic state, said fluid returns through said fluid passage from the recoil balloon into the inflation pocket, so that the inflation pocket becomes pressurized and exerts pressure against said left ventricle.

8. The device as recited in Claim 4, and further comprising a fluid injection port for injecting fluid into each of said first and second inflation pockets, wherein differing amounts of fluid may be injected into each of the inflation pockets independently, thereby permitting different pressures to be selectively applied against said first and second heart portions.

9. The device as recited in Claim 8, wherein said fluid injection port comprises two septums disposed just beneath the skin of said patient, each of which is fluidly connected through a separate fluid passage to a corresponding one of said inflation pockets.

10. The device as recited in Claim 8, wherein said fluid injection port comprises a pressurized fluid reservoir and a one-way valve, so that fluid may be automatically injected into each of the first and second inflation pockets independently, responsive to pressure in each pocket.

11. The device as recited in Claim 2, wherein the containment structure is comprised substantially entirely of a flexible, biocompatible open mesh material, having a plurality of access openings disposed therein which are distributed about an outer surface of said containment structure.

size of the heart, in order to ensure that pressure is applied by said inflation pocket against said heart at least when said heart is in a diastolic state.

19. The device as recited in Claim 14, wherein said third structure is spaced from said first structure.

20. The device as recited in Claim 14, and further comprising a drug delivery line for selectively delivering drugs to said heart through said first structure.

21. A device for treating a heart disorder, comprising:

a containment structure adapted for placement over a patient's heart;

a first inflation pocket for applying pressure against the left heart ventricle during at least a period of time when the heart is in a diastolic state;

a second inflation pocket for applying pressure against the right heart ventricle during at least a period of time when the heart is in a diastolic state; and

a fluid injection port comprising a fluid line for independently delivering pressurized fluid to each of said first and second inflation pockets, so that different pressures may be selectively applied against each of said left and right heart ventricles.

22. A device for treating a heart disorder, comprising:

a containment structure adapted for placement over a patient's heart;

an inflation pocket disposed within said containment structure for supporting a portion of the heart during at least a period of time when the heart is in a diastolic state; and

a recoil balloon disposed outwardly of said containment structure which is adapted to operate in conjunction with said inflation pocket to support the heart.

29. The device as recited in Claim 28, wherein said containment structure has an outer surface and comprises an open mesh material having a plurality of openings distributed about said outer surface, said plurality of openings providing access for visualizing coronary arteries and performing bypass procedures on said heart without removing said device.

30. The device as recited in Claim 28, wherein said plurality of inflation pockets comprise a plurality of inflation pockets which are each substantially smaller than a ventricle of said heart, and which are spaced with respect to one another, said plurality of inflation pockets together having sufficient size and being capable of applying sufficient force to restrain a heart ventricle.

31. The device as recited in Claim 30, and further comprising a fluid injection port and a fluid passage connected between said fluid injection port and each of said plurality of inflation pockets, for injecting fluid into each of said plurality of inflation pockets.

32. The device as recited in Claim 31, and further comprising a recoil balloon which is fluidly connected to each of said plurality of inflation pockets, said recoil balloon receiving fluid from said inflation pockets during a portion of the heart pumping cycle and delivering fluid to said inflation pockets during another portion of the heart pumping cycle.

33. The device as recited in Claim 32, wherein said recoil balloon is disposed at a location remote from said containment structure.

34. The device as recited in Claim 33, wherein said recoil balloon is disposed in said fluid passage, said fluid passage comprising a fluid line, said

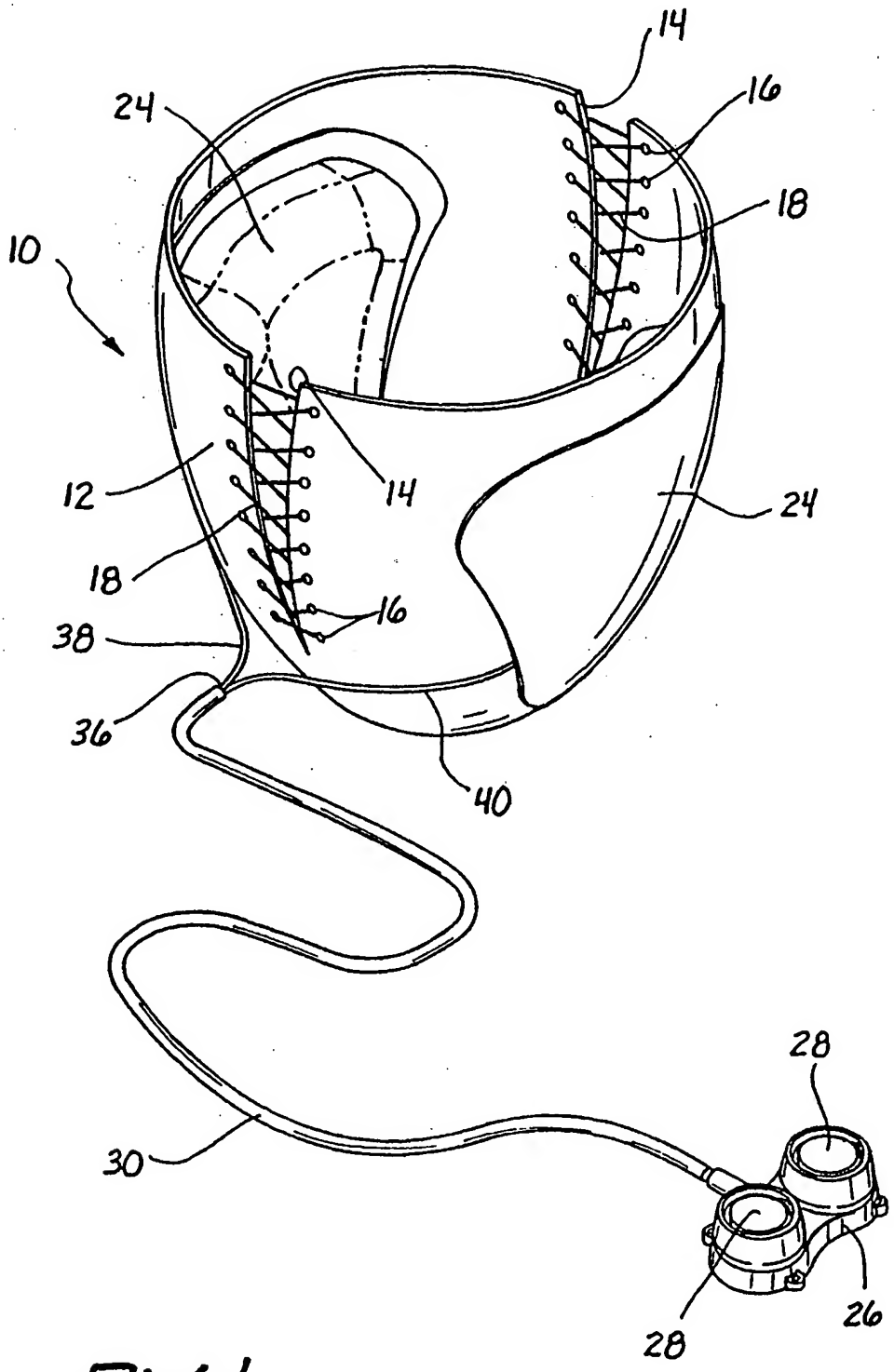


Fig. 1

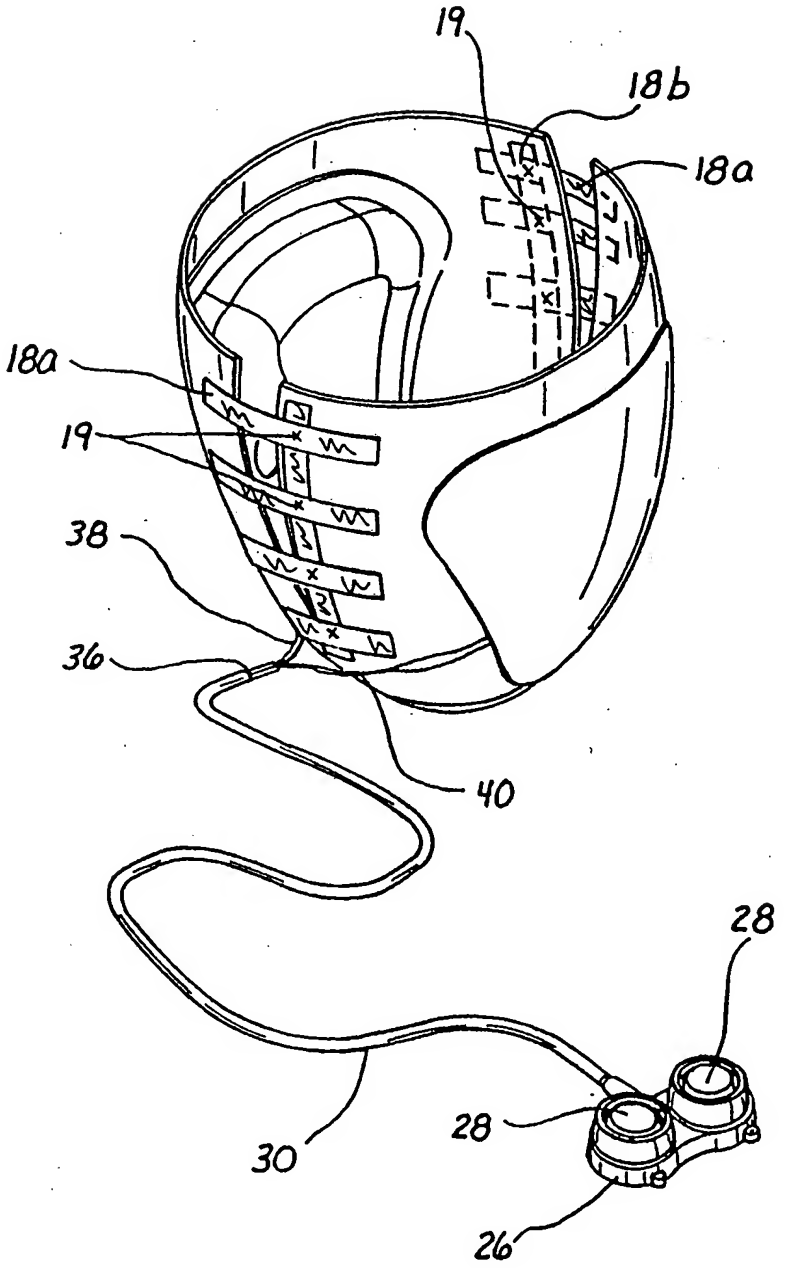


Fig. 2a

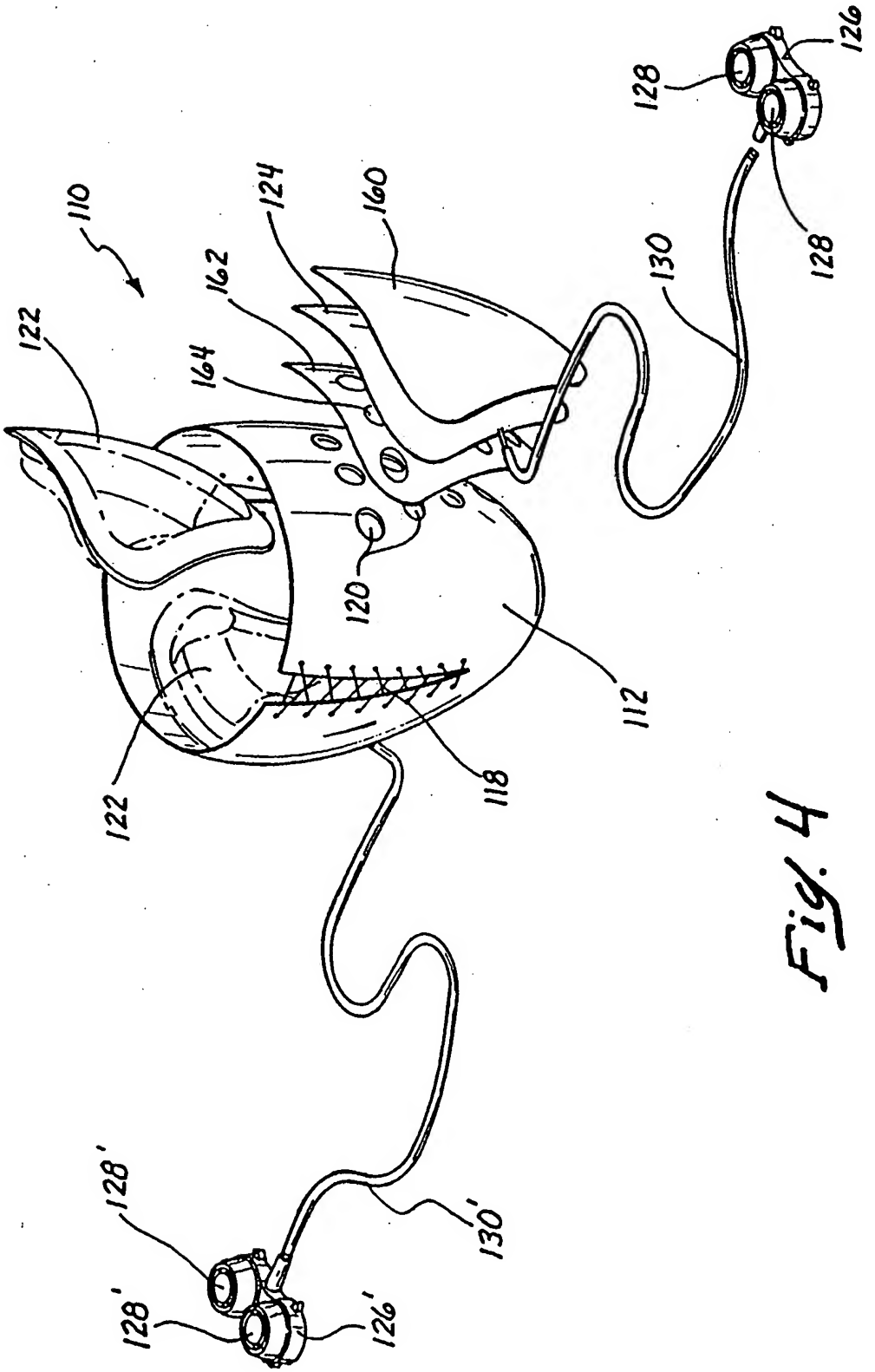

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Fig. 4

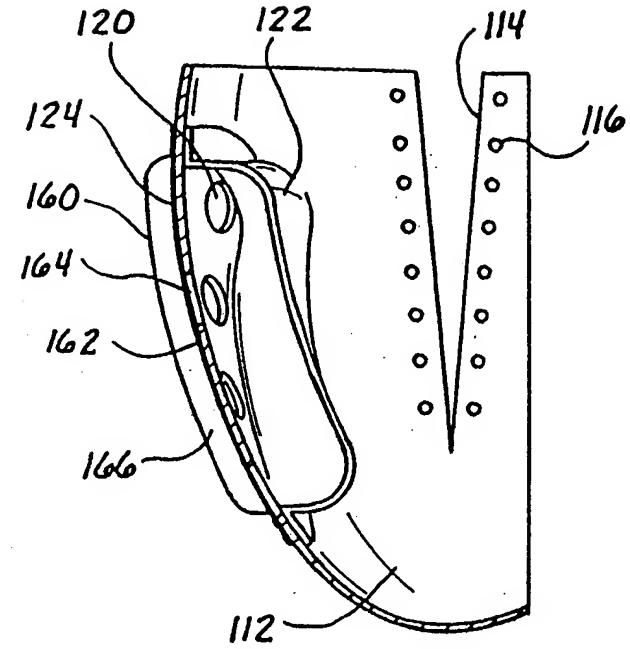

Fig. 7

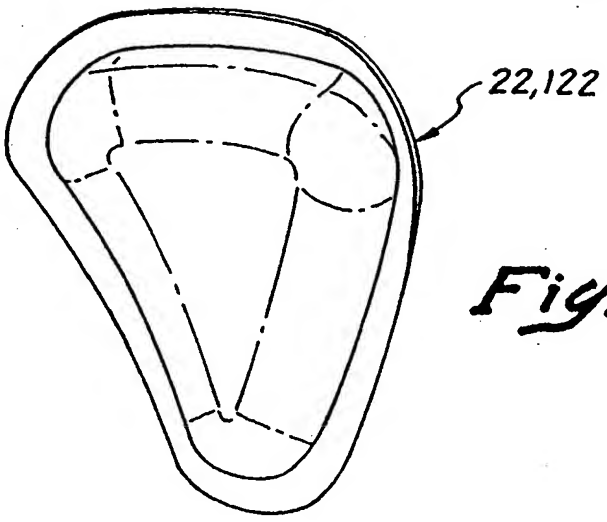

Fig. 10A

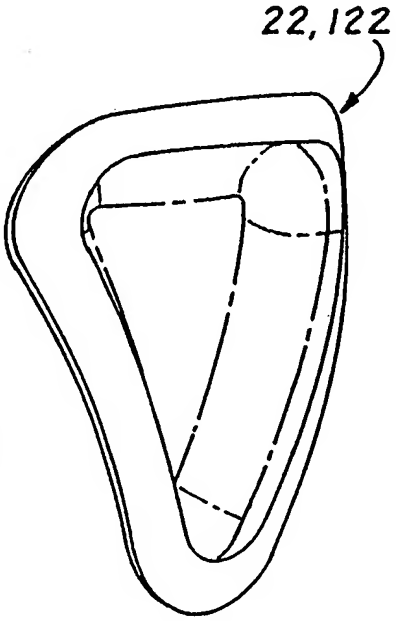

Fig. 10B

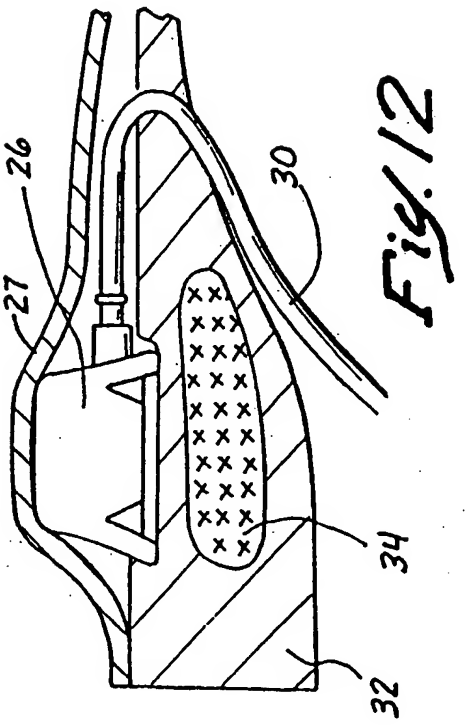

Fig. 12

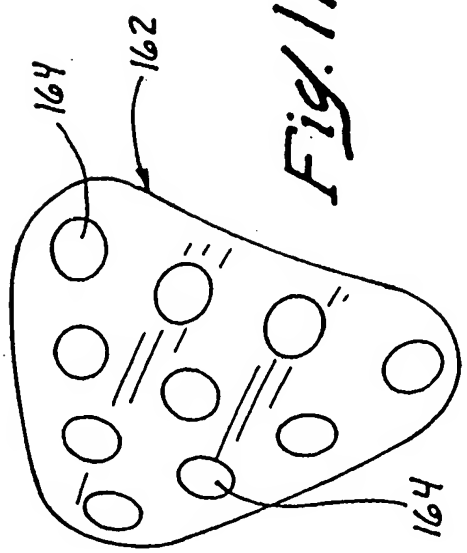

Fig. 11

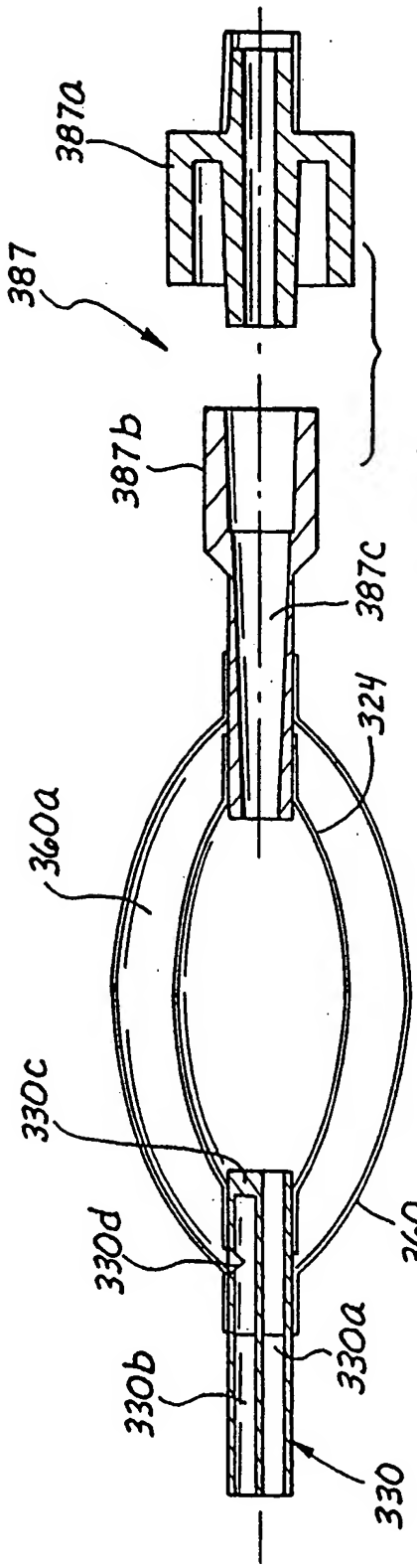

Fig. 14b

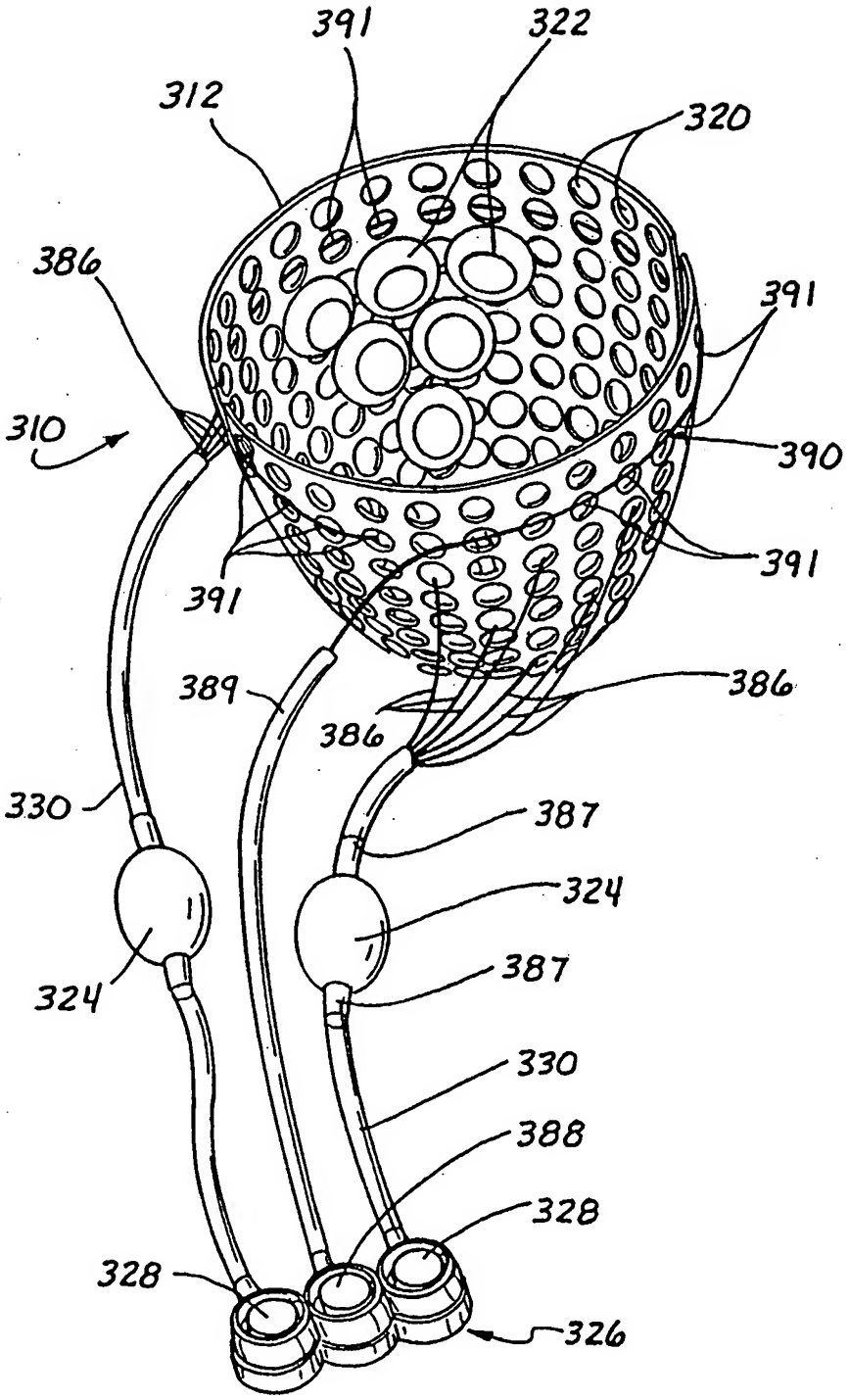
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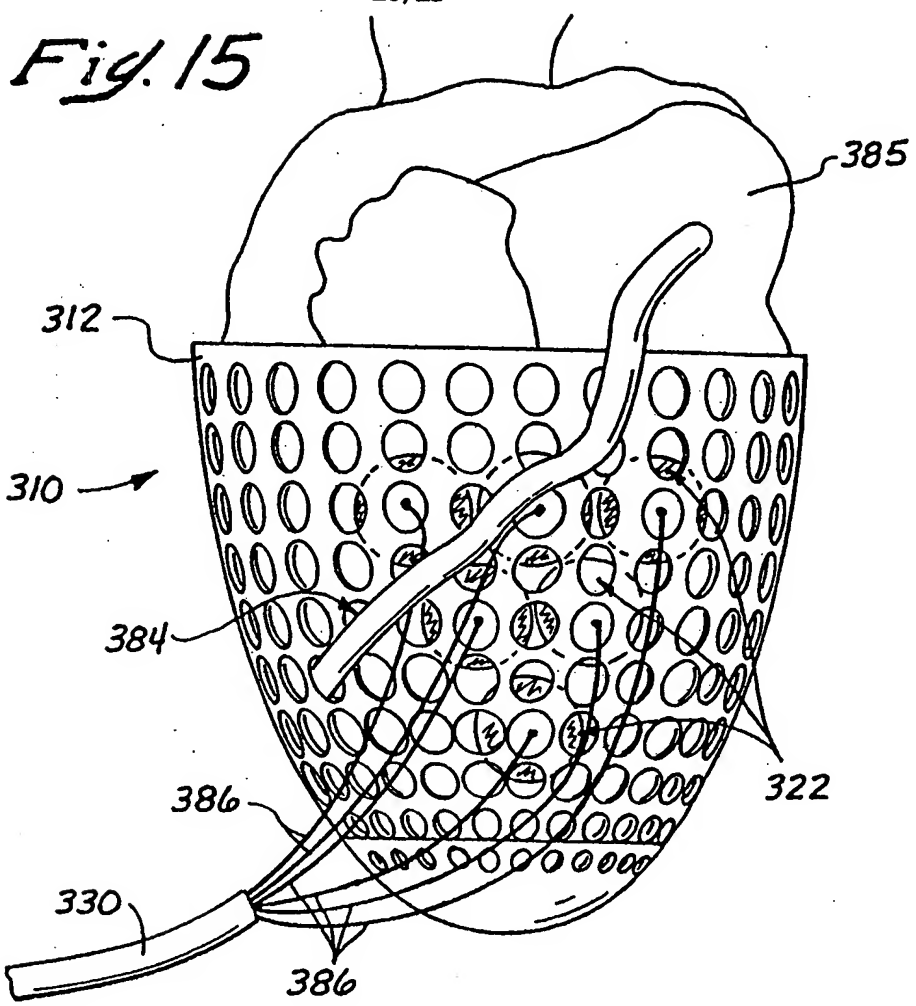
Fig. 14

Fig. 15



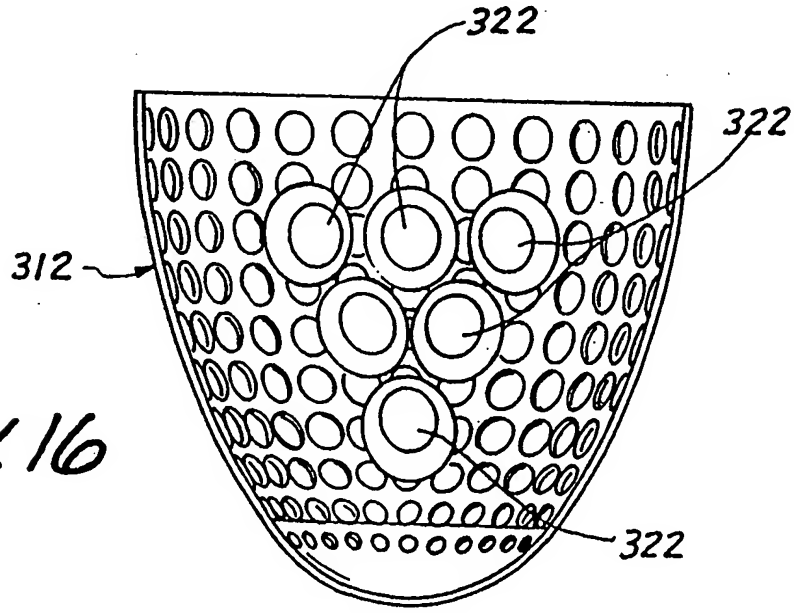


Fig. 16

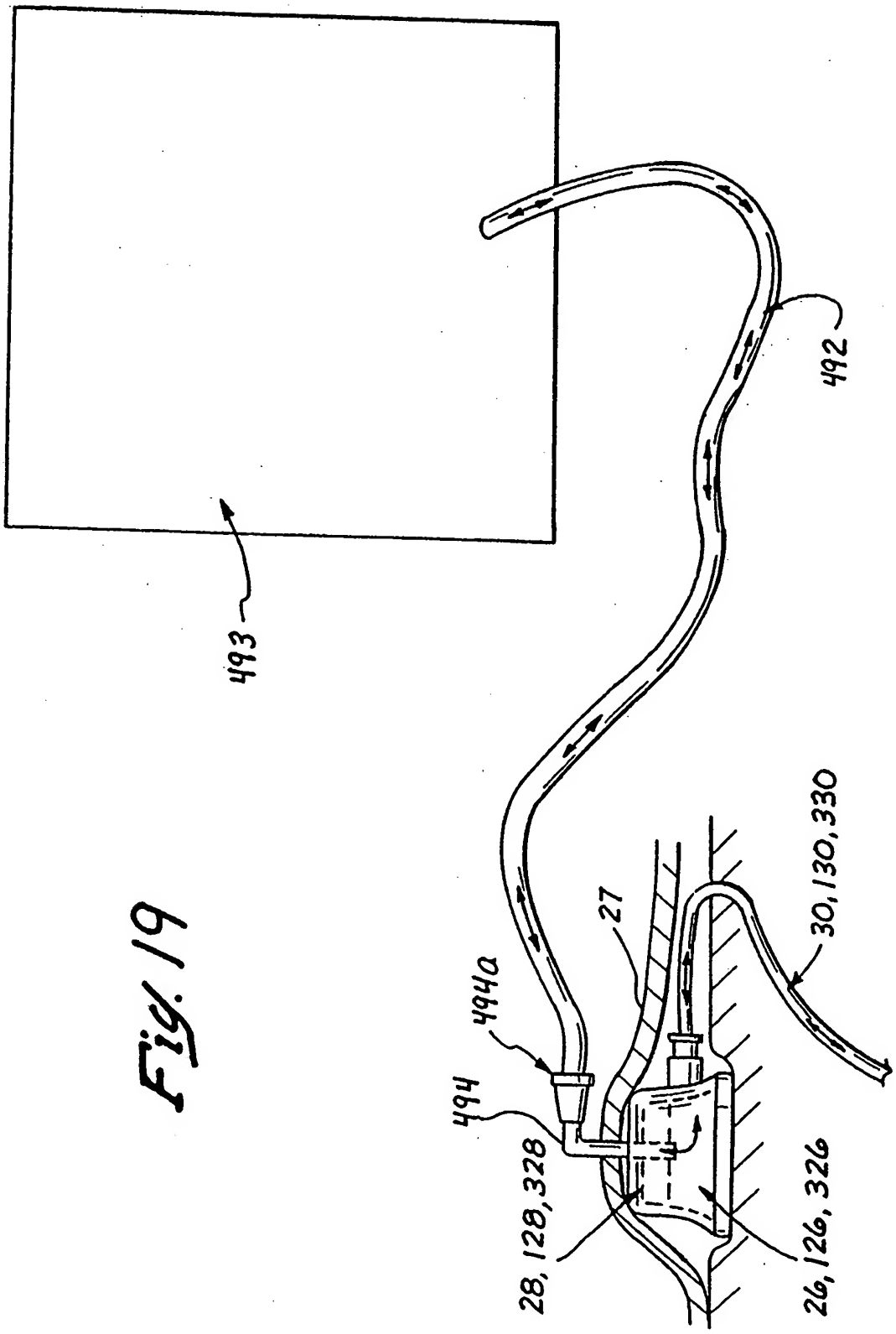


Fig. 19

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 99/30138

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/10 A61F2/00 A61F2/20 A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 169 381 A (SNYDERS ROBERT V) 8 December 1992 (1992-12-08) column 1, line 46-64 column 2, line 16 -column 3, line 26; figure 3 ---	1-4 11,12
Y	US 5 702 343 A (ALFERNESS CLIFTON A) 30 December 1997 (1997-12-30) cited in the application column 1, line 54-61 figure 3 column 7, line 16-24 ---	11
Y	WO 98 55165 A (WOODARD JOHN C ;SEARE WILLIAM J JR (US)) 10 December 1998 (1998-12-10) figure 6 --- -/--	12

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 May 2000	08.08.00

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Bichlmayer, K-P

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

In. national application No.
PCT/US 99/30138

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 23-27
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-12

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

7. Claim : 36

A dual function device for treating a heart disorder comprising a containment structure for placement over a patient's heart and further comprising at least one inflation pocket for applying pressure against a portion of said heart, a fluid injection port and a fluid passage connected between said fluid injection port and said at least one inflation pocket.